510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. **510(k) Number**
   k131126

2. **Applicant:**
   OPTI Medical Systems, Inc.

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4. **Date prepared:** June 14, 2013

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5. **Proprietary and Established Names**
   OPTI® CCA-TS2

6. **Regulatory Information**

Product Code Name	Regulation	Product Code	Class	Classification Panel
ACID, LACTIC, ENZYMATIC METHOD	862.1450	KHP	I	CHEMISTRY (75)
ELECTRODE MEASUREMENT, BLOOD GASES (PCO_2, PO_2) AND BLOOD PH	862.1120	CHL	II	CHEMISTRY (75)
SYSTEM, HEMOGLOBIN, AUTOMATED	864.5620	GKR	II	HEMATOLOGY (81)
OXIMETER, WHOLE BLOOD	864.7500	GLY	II	HEMATOLOGY (81)
ELECTRODE, ION SPECIFIC, POTASSIUM	862.1600	CEM	II	CHEMISTRY (75)
ELECTRODE, ION SPECIFIC, CALCIUM	862.1145	JFP	II	CHEMISTRY (75)
ELECTRODE, ION SPECIFIC, SODIUM	862.1665	JGS	II	CHEMISTRY (75)
ELECTRODE, ION SPECIFIC, CHLORIDE	862.1170	CGZ	II	CHEMISTRY (75)
ELECTRODE, ION SPECIFIC, UREA NITROGEN	862.1770	CDS	II	CHEMISTRY (75)
GLUCOSE OXIDASE, GLUCOSE	862.1345	CGA	II	CHEMISTRY (75)

7. **Purpose of Submission**
   OPTI Medical has designed and tested a new model (OPTI® CCA-TS2) of the OPTI® Critical Care Analyzer (OPTI® CCA-TS) previously cleared for use with k993837 for the IVD measurement of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), tHb and SO_2 and cleared for use with k093280 for lactate when used with OPTI cassettes containing the blood sample and sensors designed to interact with the analyzer to measure the parameters. Changes were made to the analyzer **only** in order to update the electronic hardware to prevent obsolescence as electronics evolve, to modify the software to operate the analyzer with modified hardware, and change the software architecture to accommodate the hardware changes and provide for modular programming in the future. No changes were made to the algorithms used to calculate parameter values. Other modifications were made to the analyzer as outlined in the table below to update the look of the new model and improve manufacturing and shipping efficiencies.

   OPTI Medical conducted studies to ensure that the OPTI® CCA-TS2 model analyzer reports equivalent results when used with the same cassettes as the OPTI® CCA-TS model analyzer predicate. The

performance tests completed are summarized here. Please note that since cassettes and the sensors used in the cassettes are unchanged from the cleared analyzer, testing specific to the cassette and the sensor chemistry such as interference studies and limit of detection studies were not repeated in this submission.

8. Predicate Device

OPTI® CCA-TS Critical Care Analyzer (k993837).

9. Device Description

The OPTI® CCA-TS2 is a modified model of the legally marketed OPTI® CCA-TS analyzer system. The OPTI® CCA-TS2 analyzer system uses the same technology and operating principles to perform the same intended uses as the OPTI® CCA-TS cleared with k993837. Optical fluorescence and reflectance technology is used to perform the parameter measurements outlined in the intended use. The technology is the same as that employed in previous models of OPTI products.

The OPTI® CCA-TS2 analyzer is sold separately from disposable cassettes containing sensors that interact with an *in-vitro* blood or plasma/serum sample aspirated into the cassette by the analyzer system. The disposable cassettes are designed and manufactured by OPTI Medical Systems, Inc. for exclusive use with OPTI Analyzers. The parameters reported by the analyzer system are determined by the sensors contained within each cassette style. Various styles of cassettes are available to report up to six combinations of blood gases, electrolytes and metabolites for each sample aspirated into the cassette. Each cassette style is bar-coded with calibration information determined for each lot of cassettes prior to release.

10. Intended Use

The OPTI CCA-TS2 system when used with disposable cassettes containing parameter specific sensors is intended to be used for the measurement of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), lactate, tHb, and SO_2 in samples of whole blood, and pH, Na^+, K^+, Ca^{++}, Cl^-, Glucose and BUN (urea) in serum and plasma, in a clinical laboratory setting or point of care locations.

- Measurements of blood gases (PCO_2, PO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
- Total hemoglobin (tHb) measurement is used to determine the hemoglobin content of human blood.
- Oxygen saturation (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.
- Potassium (K^+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
- Calcium (Ca^{++}) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
- Sodium (Na^+) measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst), adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
- Chloride (Cl^-) measurements are used in the diagnosis and treatment of electrolyte and

metabolic disorders such as cystic fibrosis and diabetic acidosis.

- Urea nitrogen (an end-product of nitrogen metabolism) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

11. Indications for Use

Same as Intended Use above.

12. Substantial Equivalence Information

Both the OPTI CCA-TS2 system and the predicate OPTI CCA-TS system use identical disposable cassettes containing electrolyte sensors to measure and report *in-vitro* results. The CCA-TS2 model is designed to use the same technology as that employed in the CCA-TS model with updated electronics and other changes to reduce manufacturing costs and add features desired by end users.

A comparison of the similarities and differences between the devices in provided in the following tables:

Similarities for OPTI® CCA-TS2 analyzer system:

Feature	Candidate: OPTI CCA-TS2 Analyzer	Predicate: OPTI CCA-TS Analyzer (k993837)
Intended use	The OPTI® CCA-TS2 system when used with disposable cassettes containing parameter specific sensors is intended to be used for the measurement of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), lactate, tHb, and SO_2 in samples of whole blood, and pH, Na^+, K^+, Ca^{++}, Cl^-, Glucose and BUN (urea) in serum and plasma, in a clinical laboratory setting or point of care locations.	Same
Measured Parameter	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), lactate, tHb, and SO_2	Same
Sample Type	Whole blood, serum, and plasma	Same
Reportable ranges	pH: 6.6 – 7.8 pH units PCO2: 10 – 200 mm Hg PO2: 10 – 700 mm Hg Na+: 100 – 180 mmol/L K+: 0.8 – 9.99 mmol/L Ca++: 0.2 – 3.0 mmol/L Cl-: 50 – 160 mmol/L Glu: 30 – 400 mg/dL BUN/Urea: 2.8 – 112.0 mg/dL Lac: 0.3 – 17.5 mmol/L tHb: 5 – 25 g/dL SO2: 60 – 100%	Same
Sample Volume	125 µL (60 µL with B60 cassette)	Same
Test consumable	One use cassette with optical fluorescence multi-sensor array Port for sample introduction Fluid waste chamber	Same

Feature	Candidate: OPTI CCA-TS2 Analyzer	Predicate: OPTI CCA-TS Analyzer (k993837)
Test consumable storage	6 – 12 months (depends on cassette style)	Same
Measurement sequence	Calibrate cassette - introduce sample - measure	Same
Measurement time	180 sec from sample introduction	Same
Measurement Temperature	37^0C	Same
Error detection	QC system to detect user errors QC system for reader self check QC system to detect cassette non-conformance	Same
Measurement Principle	Na: fluorescence K: fluorescence Ca: fluorescence Cl: fluorescence pH: fluorescence PCO2: fluorescence PO2: fluorescence glucose: fluorescence lactate: fluorescence BUN: fluorescence tHb: reflectance SO2: reflectance	Same

Differences for OPTI® CCA-TS2 analyzer system:

Feature	Candidate: OPTI CCA-TS2 Analyzer	Predicate: OPTI CCA-TS Analyzer (k993837)
Electronics - PC board	Single "System on a Chip" (SoC) processor to control all system interfaces	Multiple processor architecture with software control of interfaces (code base that was developed over 10 years ago)
Component updates to avoid obsolescence	Consolidate processors; reduce electronic components, and source motors, motor drive circuitry, gas valve module, printer, and display with updated alternatives with an estimated production life in excess of 5 years.	Some hardware components are no longer available to purchase
Power supply	16V, 3.75A	16V, 4A
Battery	Lithium Ion, 10.8V, 4000mAHr	Nickel Cadmium, 12V, 2800mAHr

Feature	Candidate: OPTI CCA-TS2 Analyzer	Predicate: OPTI CCA-TS Analyzer (k993837)
Exterior Case	Dual use handle, printer paper roller attached to lid, red accents on trim, fan replacement by user, air filter added, gas bottle housing base allows up to 16.86 mm base gas bottles.	Carry handle only, printer paper roller attached to printer, all beige exterior, fan replacement by factory service, no air filter, housing base allows up to 26.86 mm base gas bottles.
Optics module	Metal and plastic frame, plastic lenses, 3 LED common filter, standardized holodot used with all LEDs.	Metal frame, glass lenses, individual LED filters, individual holodot for each LED
Software	Architecture modified with modular components, same algorithms as predicate duplicated in new code	Architecture and code developed as single unit – limits scalability and improvement, algorithms developed for sensor and system performance
User features	System allows up to two sets of ranges that can be labeled as normal and critical. Added home screen so that users who enable security are required to log in for all functions with login timeout added.	System provides one set of user configurable ranges that may be labeled either normal or critical. System may be configured to require or not require password entry at menu level only
Gas bottle and pressure regulator	28 PSI calibration gas bottle. Regulates 30 to 5 PSI gas bottles. Adaptor ring installed to prevent use of 140 PSI gas bottle.	140 PSI calibration gas bottle, Regulates 140 to 20 PSI gas bottles, No adaptor ring installed.
Quality control	1 SRC cassette with 3 levels of LED intensity applied to assess analyzer LEDs for drift and noise over time. Replacement tHb calibration cassettes can be normalized by users.	3 identical SRC cassettes with 3 different barcodes to assess analyzer LEDs for drift and noise over time. Replacement of tHb calibration cassettes at end of shelf life frequently required return of analyzer to manufacturer for recalibration.
External communications	Serial USB connectivity. Two way communication with POCT1-A protocol	Serial RS232 connectivity. One way communication of data from analyzer only.

Modifications made to the OPTI® CCA-TS analyzer design to produce the OPTI® CCA-TS2 analyzer did not change the technological characteristics of the device and were found to be functionally equivalent.

13. Standard/Guidance Documents Referenced

- Evaluations of Precision Performance of Quantitative Measurement in Methods; Approved Guideline (CLSI guideline EP5-A2, volume 24, Number 25)
- User Verification of Performance for Precision and Trueness; Approved Guideline (CLSI guideline EP15-A2 Volume 25, Number 17)
- Method Comparison and Bias Estimation using Patient Samples; Approved Guideline (CLSI guideline EP9-A2, Volume 15, Number 19)
- Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use Part 1: General Requirements (IEC 61010-1)
- Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety

requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications (IEC 62133 Ed. 2.0 b:2012)

- Medical Device Software – Software life-cycle processes (IEC 62304:2006)
- Electrical Equipment for measurement, control and laboratory use – EMC requirements Part 2-6: Particular requirements – In-vitro diagnostic (IVD) medical equipment (IEC 61326-2-6)

14. Performance Characteristics

The modified analyzer design was assembled and tested with unchanged design cassettes with sensors to determine whether any of the design changes affected the performance, safety, or efficacy of the device. In-house studies were conducted with each type of sensor available for use on the OPTI® CCA-TS analyzer.

Method Comparison

Whole blood samples were measured across the measurement range on three OPTI CCA-TS analyzers and three OPTI CCA-TS2 analyzers at the internal site. Regression was calculated using the Ordinary linear fit method. Correlation statistics for each parameter / sensor design are presented here:

OPTI CCA-TS2 vs. Predicate in whole blood samples

Parameter	Range	Slope (95% Confidence)	Intercept	Correlation Coefficient (R^2)	n
pH	6.927 to 7.705 pH units	0.97 (0.97 to 0.98)	0.18	0.998	126
pH (dry sensor)	6.961 to 7.648 pH units	1.00 (0.98 to 1.01)	0.04	0.996	63
Sodium (Na+)	109.0 to 179.4 mmol/L	0.99 (0.98 to 0.99)	1.57	0.999	45
Potassium (K+)	0.9 to 8.1 mmol/L	1.01 (1.00 to 1.01)	-0.01	0.999	54
Calcium (Ca++)	0.28 to 2.21 mmol/L	1.00 (0.99 to 1.01)	0.00	0.999	54
Chloride (Cl-)	64.4 to 145.7 mmol/L	0.98 (0.97 to 0.99)	0.87	0.999	45
Glucose	69.4 to 361.3 mg/dL	0.99 (0.95 to 1.02)	-0.44	0.983	54
BUN (urea)	5.5 to 103.2 mg/dL	1.01 (1.00 to 1.02)	-0.20	0.999	45
pCO2	14.3 to 198.9 mmHg	0.97 (0.97 to 0.98)	0.87	0.999	117
pCO2 (dry)	14.7 to 87.9 mmHg	1.00 (0.99 to 1.02)	-1.13	0.995	63
pO2	13.5 to 639.3 mmHg	0.98 (0.98 to 0.98)	-1.82	0.999	144
pO2 (dry)	10.7 to 656.6 mmHg	0.99 (0.99 to 1.00)	0.36	0.999	66
Lactate	0.7 to 13.8 mmol/L	1.01 (0.99 to 1.03)	0.08	0.994	45
tHb	7.7 to 21.2 g/dL	1.01 (0.99 to 1.03)	-0.09	0.996	45
SO2	71.5 to 99.9 %	1.03 (1.01 to 1.06)	-3.54	0.992	63

Plasma/serum samples were measured across the measurement range on three OPTI CCA-TS analyzers and three OPTI CCA-TS2 analyzers. Correlation statistics for each parameter / sensor design are presented here:

OPTI CCA-TS2 vs. Predicate in plasma/serum samples

Parameter	Range	Slope (95% Confidence)	Intercept	Correlation Coefficient (R^2)	n
pH	6.814 to 7.741 pH units	0.97 (0.97 to 0.98)	0.21	0.999	108
Sodium (Na+)	104.1 to 176.7 mmol/L	0.98 (0.98 to 0.99)	1.91	0.998	90
Potassium (K+)	1.60 to 7.45 mmol/L	0.99 (0.99 to 1.00)	0.02	0.999	99
Calcium (Ca++)	0.39 to 2.75 mmol/L	0.98 (0.98 to 0.99)	0.02	0.999	99
Chloride (Cl-)	64.7 to 146.1 mmol/L	0.97 (0.96 to 0.97)	2.50	0.999	45
BUN (urea)	5.4 to 92.9 mg/dL	1.03 (1.01 to 1.05)	-0.53	0.995	45
Glucose	35.9 to 288.6 mg/dL	1.00 (0.98 to 1.01)	-2.32	0.997	54

In addition to the in-house studies, method comparison studies in whole blood samples were repeated at 4 different POC sites to confirm that the OPTI CCA-TS2 performs with functional equivalence to the OPTI CCA-TS analyzer. Method comparison results obtained at the 4 POC sites were very similar to the results obtained at the internal site.

Precision/Reproducibility

Multi-day, in-house, precision testing was performed in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Samples consisted of three levels of aqueous quality control solution for the testing (OPTI Check Level 1, Level 2 and Level 3 manufactured by Bionostics Inc., Acton, Massachusetts). Testing was performed over at least 10 days, 4 runs per day, with a minimum of 2 OPTI CCA-TS2 analyzers.

Precision OPTI CCA-TS2 with controls

	PO2 (mmHg)			**Dry PO2 (mmHg)**		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	20	20	20
Total Average	71.6	100.0	137.7	73.5	103.5	139.1
Within Run St.Dev (S_{wr})	1.3	1.4	1.4	1.4	0.9	1.4
Within Run %CV	1.8%	1.4%	1.0%	1.8%	0.9%	1.0%
Between Run St.Dev (S_{rr})	0.0	0.9	1.0	0.0	0.4	0.6
Between Run %CV	0.0%	0.9%	0.7%	0.0%	0.4%	0.5%
Between Day St.Dev (S_{dd})	0.8	0.0	0.6	1.1	0.9	1.4
Between Day %CV	1.1%	0.0%	0.4%	1.5%	0.9%	1.0%
Total Precision St.Dev (S_T)	1.5	1.7	1.8	1.6	1.3	2.0
Total %CV	2.1%	1.7%	1.3%	2.2%	1.3%	1.5%

	PCO2 (mmHg)			Dry PCO2 (mmHg)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	20	20	20
Total Average	74.5	45.0	24.8	72.6	43.1	22.5
Within Run St.Dev (S_{wr})	0.8	0.3	0.3	0.8	0.3	0.3
Within Run %CV	1.1%	0.7%	1.1%	1.1%	0.7%	1.4%
Between Run St.Dev (S_{rr})	0.2	0.2	0.1	0.0	0.1	0.1
Between Run %CV	0.2%	0.5%	0.5%	0.0%	0.3%	0.2%
Between Day St.Dev (S_{dd})	0.4	0.3	0.2	0.9	0.5	0.3
Between Day %CV	0.5%	0.6%	0.8%	1.2%	1.1%	1.4%
Total Precision St.Dev (S_T)	0.9	0.5	0.4	1.2	0.6	0.4
Total %CV	1.3%	1.0%	1.5%	1.6%	1.3%	2.0%

	pH			Dry pH		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	20	20	20
Total Average	7.151	7.415	7.624	7.168	7.418	7.632
Within Run St.Dev (S_{wr})	0.003	0.006	0.005	0.011	0.008	0.007
Within Run %CV	0.0%	0.1%	0.1%	0.2%	0.1%	0.1%
Between Run St.Dev (S_{rr})	0.001	0.002	0.002	0.007	0.003	0.004
Between Run %CV	0.0%	0.0%	0.0%	0.1%	0.0%	0.1%
Between Day St.Dev (S_{dd})	0.003	0.003	0.004	0.009	0.007	0.008
Between Day %CV	0.0%	0.0%	0.1%	0.1%	0.1%	0.1%
Total Precision St.Dev (S_T)	0.005	0.007	0.007	0.015	0.011	0.011
Total %CV	0.1%	0.1%	0.1%	0.2%	0.1%	0.1%

	Na+ (mmol/L)			K+ (mmol/L)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	20	20	20
Total Average	126.1	143.7	156.5	2.92	4.86	5.92
Within Run St.Dev (S_{wr})	0.6	0.7	0.4	0.03	0.03	0.03
Within Run %CV	0.4%	0.5%	0.3%	0.9%	0.6%	0.5%
Between Run St.Dev (S_{rr})	0.2	0.0	0.0	0.00	0.01	0.00
Between Run %CV	0.2%	0.0%	0.0%	0.0%	0.1%	0.0%
Between Day St.Dev (S_{dd})	0.3	0.1	0.4	0.01	0.01	0.02
Between Day %CV	0.3%	0.1%	0.3%	0.5%	0.2%	0.4%
Total Precision St.Dev (S_T)	0.7	0.7	0.6	0.03	0.03	0.04
Total %CV	0.6%	0.5%	0.4%	1.0%	0.6%	0.6%

	Ca++ (mmol/L)			Cl- (mmol/L)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	10	10	10
Total Average	1.57	1.27	0.79	95.3	107.1	115.6
Within Run St.Dev (S_{wr})	0.01	0.01	0.01	0.6	1.4	0.5

	Ca++ (mmol/L)			Cl- (mmol/L)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Within Run %CV	0.9%	0.7%	0.9%	0.7%	1.3%	0.4%
Between Run St.Dev (S_{rr})	0.01	0.00	0.00	0.3	0.0	0.2
Between Run %CV	0.4%	0.3%	0.4%	0.3%	0.0%	0.2%
Between Day St.Dev (S_{dd})	0.02	0.01	0.01	0.2	0.2	0.3
Between Day %CV	1.2%	0.7%	1.2%	0.2%	0.2%	0.3%
Total Precision St.Dev (S_T)	0.02	0.01	0.01	0.7	1.4	0.6
Total %CV	1.5%	1.0%	1.5%	0.8%	1.3%	0.5%

	Glucose (mg/dL)			BUN (mg/dL)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	10	10	10	10	10	10
Total Average	40.5	95.7	316.2	74.1	19.3	5.9
Within Run St.Dev (S_{wr})	1.6	3.5	7.5	3.0	0.6	0.1
Within Run %CV	3.9%	3.6%	2.4%	4.0%	3.2%	1.9%
Between Run St.Dev (S_{rr})	1.1	1.7	3.4	1.8	0.3	0.1
Between Run %CV	2.6%	1.7%	1.1%	2.4%	1.7%	2.5%
Between Day St.Dev (S_{dd})	1.4	2.2	4.6	0.0	0.0	0.0
Between Day %CV	3.5%	2.3%	1.4%	0.0%	0.0%	0.7%
Total Precision St.Dev (S_T)	2.4	4.4	9.4	3.5	0.7	0.2
Total %CV	5.9%	4.6%	3.0%	4.7%	3.7%	3.2%

	Lactate (mmol/L)			tHb (g/dL)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20	20	20	20
Total Average	1.02	2.50	4.59	20.7	14.0	8.9
Within Run St.Dev (S_{wr})	0.06	0.11	0.18	0.1	0.1	0.1
Within Run %CV	5.6%	4.2%	4.0%	0.3%	0.4%	1.2%
Between Run St.Dev (S_{rr})	0.00	0.03	0.09	0.0	0.0	0.0
Between Run %CV	0.0%	1.3%	2.0%	0.1%	0.3%	0.0%
Between Day St.Dev (S_{dd})	0.04	0.02	0.09	0.2	0.1	0.2
Between Day %CV	3.4%	0.9%	2.0%	0.8%	0.6%	2.2%
Total Precision St.Dev (S_T)	0.07	0.11	0.22	0.2	0.1	0.2
Total %CV	6.4%	4.5%	4.8%	0.9%	0.8%	2.5%

	SO2 (%)		
	OPTI-Check Level 1	OPTI-Check Level 2	OPTI-Check Level 3
Days run	20	20	20
Total Average	81.2	89.8	96.4
Within Run St.Dev (S_{wr})	0.1	0.3	0.4
Within Run %CV	0.2%	0.3%	0.4%
Between Run St.Dev (S_{rr})	0.1	0.0	0.0
Between Run %CV	0.1%	0.0%	0.0%
Between Day St.Dev (S_{dd})	0.5	0.5	0.6
Between Day %CV	0.6%	0.5%	0.7%
Total Precision St.Dev (S_T)	0.5	0.5	0.7
Total %CV	0.6%	0.6%	0.8%

In addition, within-run precision testing was performed in-house in accordance with CLSI EP5-A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline – Second Edition. Samples consisted of three levels of whole blood spiked or diluted to give three levels of each of the analytes. Testing was performed in one day with 10 repeats at each blood level on one OPTI CCA-TS2 analyzer. Results of the studies run are shown in the tables below:

Precision OPTI CCA-TS2 with whole blood

Blood Gases

	Standard Sampling PO2 (mmHg)			60µL Sampling PO2 (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	54.8	90.3	434.5	52.7	92.6	445.2
Standard Deviation	0.5	0.5	5.1	0.4	0.6	4.9
%CV	0.97%	0.52%	1.18%	0.68%	0.60%	1.10%

	Dry PO2 (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	55.9	91.8	428.7
Standard Deviation	0.6	0.5	5.8
%CV	1.02%	0.57%	1.36%

	Standard Sampling PCO2 (mmHg)			60µL Sampling PCO2 (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	21.4	46.2	91.6	45.6	21.1	92.4
Standard Deviation	0.3	0.4	1.7	0.5	0.4	1.3
%CV	1.60%	0.90%	1.82%	1.15%	1.73%	1.37%

	Dry PCO2 (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	19.6	44.4	92.8
Standard Deviation	0.357	0.316	1.088
%CV	1.82%	0.71%	1.17%

	Standard Sampling pH (mmHg)			60µL Sampling pH (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	7.134	7.341	7.518	7.341	7.521	7.132
Standard Deviation	0.004	0.006	0.009	0.005	0.006	0.003
%CV	0.05%	0.08%	0.13%	0.07%	0.08%	0.04%

	Dry pH (mmHg)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	7.174	7.352	7.558
Standard Deviation	0.011	0.019	0.012
%CV	0.16%	0.26%	0.17%

	SO2		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	79.5	96.8	99.9
Standard Deviation	0.2	0.1	0.0
%CV	0.21%	0.05%	0.00%

Electrolytes, Glucose and BUN

	Na+ (mmol/L)			K+ (mmol/L)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	136.5	167.4	112.7	3.6	8.1	2.1
Standard Deviation	0.4	0.2	0.4	0.0	0.0	0.1
%CV	0.26%	0.13%	0.33%	0.38%	0.26%	2.49%

	Cl- (mmol/L)			Ca++ (mmol/L)		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	104.1	141.3	57.5	1.2	2.6	0.8
Standard Deviation	0.3	1.0	0.3	0.0	0.0	0.0
%CV	0.28%	0.73%	0.51%	0.35%	0.40%	0.59%

	Glucose			BUN		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	82.7	166.1	34.6	6.03	26.61	85.59
Standard Deviation	3.8	8.2	2.4	0.03	0.25	0.97
%CV	4.65%	4.91%	6.94%	0.53%	0.93%	1.13%

Lactate

	Lactate		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	3.85	1.13	6.17
Standard Deviation	0.14	0.05	0.20
%CV	3.76%	4.42%	3.16%

tHb

	tHb		
	Whole Blood Level 1	Whole Blood Level 2	Whole Blood Level 3
Total Average	7.5	17.7	12.1
Standard Deviation	0.2	0.2	0.2
%CV	2.59%	1.34%	1.86%

Linearity / Reportable range

The linearity of the OPTI CCA-TS2 system was determined using the experimental protocol recommended in CLSI guideline EP15-A2, User Verification of Performance for Precision and Trueness; Approved Guideline. Linearity data was collected versus the OPTI CCA-TS analyzer predicate using standard aqueous linearity solutions (CVC123 manufactured by RNA Medical, Devons, MA) and whole blood samples that included points just outside the measurement range and points inside the range. Each of the levels of samples was run on two (2) OPTI CCA-TS and two (2) OPTI CCA-TS2 analyzers. The linear regression correlation between analyzers using each individual measurement is summarized below:

Parameter	Sample type	Range	Slope (95% Confidence)	Intercept	Correlation Coefficient (R^2)	n
pH (60µL sample)	Whole Blood	6.391 to 8.044 pH units	0.97 (0.96 to 0.97)	0.26	0.999	81
pH (120 µL)	Whole Blood	6.404 to 8.011 pH units	0.98 (0.97 to 0.98)	0.16	1.000	81
pH (dry sensor)	Whole Blood	6.477 to 7.915 pH units	0.99 (0.98 to 1.00)	0.09	0.998	81
pH (60µL sample)	CVC123	6.915 to 7.638 pH units	0.98 (0.98 to 0.99)	0.14	1.000	24
pH (120 µL)	CVC123	6.912 to 7.646 pH units	0.96 (0.96 to 0.97)	0.26	0.999	48
pH (dry sensor)	CVC123	6.971 to 7.631 pH units	0.98 (0.97 to 0.99)	0.16	0.999	24
PCO2 (60µL sample)	Whole Blood	6.2 to 256.6 mmHg	0.98 (0.98 to 0.99)	0.65	1.000	81
PCO2 (120µL)	Whole Blood	7.4 to 205.7 mmHg	0.98 (0.98 to 0.99)	0.45	1.000	72
PCO2 (dry)	Whole Blood	2.2 to 207.9 mmHg	1.01 (1.00 to 1.02)	-1.19	0.999	81

Parameter	Sample type	Range	Slope (95% Confidence)	Intercept	Correlation Coefficient (R^2)	n
PCO2 (60µL sample)	CVC123	13.9 to 85.8 mmHg	0.98 (0.97 to 0.99)	0.35	1.000	30
PCO2 (120µL)	CVC123	13.3 to 90.5 mmHg	0.98 (0.98 to 0.99)	0.88	0.999	60
PCO2 (dry)	CVC123	15.9 to 87.8 mmHg	0.99 (0.98 to 1.00)	-0.04	1.000	30
PO2 (60µL sample)	Whole Blood	6.8 to 711.2 mmHg	0.99 (0.99 to 1.00)	-3.10	0.999	90
PO2 (120µL)	Whole Blood	8.9 to 707.0 mmHg	0.99 (0.98 to 0.99)	-2.57	1.000	90
PO2 (dry)	Whole Blood	9.1 to 656.6 mmHg	0.99 (0.99 to 1.00)	0.43	0.999	72
PO2 (60µL sample)	CVC123	62.7 to 451.0 mmHg	0.97 (0.97 to 0.98)	0.29	0.999	30
PO2 (120µL)	CVC123	60.9 to 487.1 mmHg	0.98 (0.97 to 0.99)	0.90	.0999	60
PO2 (dry)	CVC123	60.8 to 476.3 mmHg	0.98 (0.97 to 0.99)	2.55	1.000	30
Sodium (Na+)	Whole Blood	93.4 to 204.4 mmHg	1.00 (0.99 to 1.01)	-0.18	1.000	63
Sodium (Na+)	CVC123	116.2 to 163.8 mmol/L	1.01 (0.99 to 1.02)	-0.68	0.998	36
Potassium (K+)	Whole Blood	0.39 to 10.09 mmol/L	1.00 (1.00 to 1.01)	0.00	1.000	72
Potassium (K+)	CVC123	1.19 to 6.98 mmol/L	0.99 (0.99 to 1.00)	0.10	1.000	48
Calcium (Ca++)	Whole Blood	0.158 to 3.372 mmol/L	0.99 (0.99 to 0.99)	0.01	1.000	72
Calcium (Ca++)	CVC123	0.20 to 2.67 mmol/L	1.01 (1.00 to 1.02)	-0.00	0.999	30
Chloride (Cl-)	Whole Blood	42.9 to 175.0 mmol/ L	0.99 (0.98 to 1.00)	-0.21	0.999	63
Chloride (Cl-)	CVC123	85.9 to 135.0 mmol/L	0.96 (0.94 to 0.98)	2.93	0.998	30
Glucose	Whole Blood	12.5 to 455.6 mg/dL	1.02 (1.00 to 1.05)	-4.19	0.991	63
Glucose	CVC123	81.8 to 303.6 mg/dL	0.98 (0.94 to 1.03)	1.87	0.993	18
BUN (urea)	Whole Blood	2.63 to 142.93 mg/dL	1.00 (0.99 to 1.01)	0.08	0.999	63
Lactate	Whole Blood	0.17 to 17.81 mmol/L	1.04 (1.02 to 1.06)	-0.02	0.996	55
Lactate	CVC123	0.77 to 15.3 mmol/L	1.03 (1.00 to 1.06)	-0.14	0.995	30
tHb	Whole Blood	4.37 to 26.13 g/dL	0.99 (0.98 to 1.01)	0.10	0.998	63
SO2	Whole Blood	55.5 to 99.9 %	0.96 (0.94 to 0.98)	3.23	0.991	72

The linearity data support the following reportable range claims:

pH: 6.6 – 7.8 pH units	Cl-: 50 - 160 mmol/L
PCO2: 10 – 200 mm Hg	Glu: 30 – 400 mg/dL
PO2: 10 – 700 mm Hg	BUN/Urea: 208 – 112.0 mg/dL
Na+: 100 – 180 mmol/L	Lac: 0.3 – 17.5 mmol/L
K+: 0.8 – 9.99 mmol/L	tHb: 5 – 25 g/dL
Ca++: 0.2 – 3.0 mmol/L	SO2: 60 – 100%

Limit of Blank, Limit of Determination and Limit of Quantitation

No changes were made to the electrolyte sensors installed in the disposable cassettes used on both the OPTI CCA-TS2 device and the predicate OPTI CCA-TS so evaluation of limits of detection does not apply to the analyzer change.

Analytical Specificity / Interferences

No changes were made to the electrolyte sensors installed in the disposable cassettes used on both the OPTI CCA-TS2 device and the predicate OPTI CCA-TS. Evaluation of interferences was not performed since the analysis was done previously in k993837.

Traceability

The parameters measured and reported by the OPTI CCA-TS2 device are calibrated and tested for release using primary and secondary standards that are traceable to NIST or other recognized standards (where no NIST standard is available of practical) as outlined in this table:

Analyte	Traceability
pH	Standard reference material: NIST traceable phosphate buffer; buffer solution made with NIST HEPES SRM 2181 + 2182
PO2	NIST traceable pure gases gravimetrically prepared
PCO2	NIST traceable pure gases gravimetrically prepared
Na	Standard reference material, NIST SRM 956A
K	Standard reference material, NIST SRM 956A
Ca	Standard reference material, NIST SRM 956A
Cl	Standard reference material, NIST SRM 956A
tHb	Definition of SI unit by French: Conférence générale des poids et mesures (CGPM), International Siggaard-Andersen Model

Analyte	Traceability
SO2	Definition of SI unit by French: Conférence générale des poids et mesures (CGPM) , International Siggaard-Andersen Model
Glu	Standard reference material, NIST SRM 965
BUN	Standard reference material, NIST SRM 909
Lactate	Gravimetric working calibrator prepared from sodium L-lactate >99% purity

15. Electromagnetic Compatibility and Electrical Safety

Electromagnetic Compatibility and electrical safety tests were performed on the OPTI® CCA-TS2 model to show compliance with current standards applicable for the device. Performance verification studies were performed using the modified device with all cassette styles and modified consumables and calibration methods to demonstrate performance equivalence.

16. Software Verification and Validation

The software driving the analyzer has been updated according to internal design control and verification procedures of the Quality System at OPTI Medical Systems, Inc. to ensure changes did not impact the measurements reported by the analyzer system.

17. Conclusion

Analysis of the method comparison data collected during internal and POC site studies for this device presented in this 510(k), together with the linearity and precision data collected during internal and POC studies demonstrates that the OPTI CCA-TS2 device is safe, effective, and substantially equivalent to the OPTI CCA-TS predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

OPTI Medical Systems, Inc.
C/O Len Owens
235 Hembree Park Drive
ROSWELL GA 30076

Re: K131126
Trade/Device Name: OPTI CCA-TS2
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (PCO2, PO2) and blood pH test system
Regulatory Class: II
Product Code: KHP, CHL, GKR, GLY, CEM, JFP, JGS, CGZ, CDS, CGA
Dated: July 11, 2013
Received: July 16, 2013

Dear Mr. Owens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k131126

Device Name: OPTI CCA-TS2

Indications for Use: -
The OPTI CCA-TS2 system when used with disposable cassettes containing parameter specific sensors is intended to be used for the measurement of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), lactate, tHb, and SO_2 in samples of whole blood, and pH, Na^+, K^+, Ca^{++}, Cl^-, Glucose and BUN (urea) in serum and plasma, in a clinical laboratory setting or point of care locations.

- Measurements of blood gases (PCO_2, PO_2) and blood pH are used in the diagnosis and treatment of life-threatening acid-base disturbances.
- Lactate (lactic acid) measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).
- Total hemoglobin (tHb) measurement is used to determine the hemoglobin content of human blood.
- Oxygen saturation (SO2) measurement is used to determine the oxygen capacity of the hemoglobin.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

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Office of In Vitro Diagnostics and Radiological Health (OIR)

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- Potassium (K^+) measurements are used to monitor electrolyte balance in the diagnosis and treatment of diseases conditions characterized by low or high blood potassium levels.
- Calcium (Ca^{++}) measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).
- Sodium (Na^+) measurements are used in the diagnosis and treatment of aldosteronism (excessive secretion of the hormone aldosterone), diabetes insipidus (chronic excretion of large amounts of dilute urine, accompanied by extreme thirst),adrenal hypertension, Addison's disease (caused by destruction of the adrenal glands), dehydration, inappropriate antidiuretic hormone secretion, or other diseases involving electrolyte imbalance.
- Chloride (Cl^-) measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.
- Urea nitrogen (an end-product of nitrogen metabolism) measurements are used in the diagnosis and treatment of certain renal and metabolic diseases.
- Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

Prescription Use _x_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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